

§ 520.2260c

21 CFR Ch. I (4–1–13 Edition)

spp.; colibacillosis (bacterial scours) caused by *Escherichia coli*; coccidiosis caused by *Eimeria bovis* and *E. zurnii*; and calf diphtheria caused by *Fusobacterium necrophorum*.

(iii) *Limitations*. Do not use in calves to be slaughtered under 1 month of age or calves being fed an all milk diet. Do not use in female dairy cattle 20 months of age or older. If symptoms persist after 3 days, consult a veterinarian. Do not administer more than 2 consecutive doses. Do not slaughter animals for food for at least 8 days after the last dose. Do not crush bolus.

[46 FR 36132, July 14, 1981, as amended at 48 FR 18803, Apr. 26, 1983; 48 FR 32760, July 19, 1983; 49 FR 29057, July 18, 1984; 50 FR 49372, Dec. 2, 1985; 51 FR 30212, Aug. 25, 1986; 53 FR 40727, Oct. 18, 1988; 54 FR 14341, Apr. 11, 1989; 55 FR 8462, Mar. 8, 1990; 56 FR 50653, Oct. 8, 1991; 59 FR 22754, May 3, 1994; 61 FR 4875, Feb. 9, 1996; 62 FR 35076, June 30, 1997; 66 FR 14073, Mar. 9, 2001; 68 FR 4915, Jan. 31, 2003; 70 FR 8290, Feb. 18, 2005; 78 FR 17596, Mar. 22, 2013]

§ 520.2260c Sulfamethazine sustained-release tablets.

(a) *Sponsor*. See No. 053501 in § 510.600(c) of this chapter for use of an 8-gram sulfamethazine sustained-release tablet.

(b) *Conditions of use*—(1) *Amount*. 8 grams (1 tablet) per 45 pounds of body weight as a single dose.

(2) *Indications for use*. In calves for sustained treatment of pneumonia caused by *Pasteurella* spp., colibacillosis (bacterial scours) caused by *Escherichia coli*; and calf diphtheria caused by *Fusobacterium necrophorum*.

(3) *Limitations*. If there is no response within 2 to 3 days, reevaluate therapy. Do not crush tablets. Treated animals must not be slaughtered for food within 18 days after the latest treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[48 FR 26763, June 10, 1983, as amended at 56 FR 50653, Oct. 8, 1991; 59 FR 22754, May 3, 1994; 61 FR 4875, Feb. 9, 1996]

§ 520.2261 Sulfamethazine sodium oral dosage forms.

§ 520.2261a Sulfamethazine solution.

(a) *Sponsors*. See Nos. 000010 and 061623 in § 510.600(c) of this chapter for

use of a 12.5-percent sulfamethazine sodium solution.

(b) *Related tolerances in edible products*. See § 556.670 of this chapter.

(c) *Conditions of use*—(1) *Amount*. Administer in drinking water to provide: Cattle and swine 112.5 milligrams of sulfamethazine sodium per pound of body weight per day on the first day and 56.25 milligrams per pound of body weight on subsequent days; Chickens, 61 to 89 milligrams of sulfamethazine sodium per pound of body weight per day, and turkeys 53 to 130 milligrams of sulfamethazine sodium per pound of body weight per day, depending upon the dosage, age, and class of chickens or turkeys, ambient temperature, and other factors.

(2) *Indications for use*. For treatment and control of diseases caused by organisms sensitive to sulfamethazine.

(i) *Beef and nonlactating dairy cattle*. Treatment of bacterial pneumonia and bovine respiratory disease complex (shipping fever complex) (*Pasteurella* spp.), colibacillosis (bacterial scours) (*Escherichia coli*), necrotic pododermatitis (foot rot) (*Fusobacterium necrophorum*), calf diphtheria (*Fusobacterium necrophorum*), acute mastitis (*Streptococcus* spp.), and acute metritis (*Streptococcus* spp.).

(ii) *Swine*. Treatment of porcine colibacillosis (bacterial scours) (*Escherichia coli*), and bacterial pneumonia (*Pasteurella* spp.).

(iii) *Chickens and turkeys*. In chickens for control of infectious coryza (*Avibacterium paragallinarum*), coccidiosis (*Eimeria tenella*, *Eimeria necatrix*), acute fowl cholera (*Pasteurella multocida*), and pullorum disease (*Salmonella pullorum*). In turkeys for control of coccidiosis (*Eimeria meleagritidis*, *Eimeria adenoides*). Medicate as follows: Infectious coryza in chickens, medicate for 2 consecutive days; acute fowl cholera and pullorum disease, in chickens, medicate for 6 consecutive days; coccidiosis, in chickens and turkeys, medicate as in paragraph (c) of this section, then reduce amount of medication to one-half for 4 additional days.

(3) *Limitations*. Add the required dose to that amount of water that will be consumed in 1 day. Consumption should be carefully checked. Have only

medicated water available during treatment. Withdraw medication from cattle, chickens, and turkeys 10 days prior to slaughter for food. Withdraw medication from swine 15 days before slaughter for food. Do not medicate chickens or turkeys producing eggs for human consumption. Treatment of all diseases should be instituted early. Treatment should continue 24 to 48 hours beyond the remission of disease symptoms, but not to exceed a total of 5 consecutive days in cattle or swine. Medicated cattle, swine, chickens, and turkeys must actually consume enough medicated water which provides the recommended dosages. Do not use in female dairy cattle 20 months of age or older. Use of sulfamethazine in this class of cattle may cause milk residues. A withdrawal period has not been established in prerinuating calves. Do not use in calves to be processed for veal.

(d) *NAS/NRC status.* The conditions of use specified in this section have been reviewed by NAS/NRC and are found effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

[47 FR 25322, June 11, 1982, as amended at 47 FR 25735, June 15, 1982; 67 FR 78355, Dec. 24, 2002; 70 FR 32489, June 3, 2005; 74 FR 36112, July 22, 2009; 75 FR 10166, Mar. 5, 2010; 76 FR 17337, Mar. 29, 2011]

§ 520.2261b Sulfamethazine powder.

(a) *Specifications.* A soluble powder composed of 100 percent sulfamethazine sodium.

(b) *Sponsors.* See Nos. 000010 and 061623 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.670 of this chapter.

(d) *Conditions of use—(1) Chickens—(i) Amount.* Administer in drinking water to provide 58 to 85 milligrams (mg) per pound (lb) of body weight per day.

(ii) *Indications for use.* For control of infectious coryza (*Haemophilus gallinarum*), coccidiosis (*Eimeria tenella*, *E. necatrix*), acute fowl cholera (*Pasteurella multocida*), and pullorum disease (*Salmonella pullorum*).

(iii) *Limitations.* Add the required dose to that amount of water that will be consumed in 1 day. Consumption

should be carefully checked. Have only medicated water available during treatment. Withdraw medication 10 days prior to slaughter for food. Do not medicate chickens producing eggs for human consumption. Treatment of all diseases should be instituted early. Treatment should continue 24 to 48 hours beyond the remission of disease symptoms. Medicated chickens must actually consume enough medicated water which provides the recommended dosages.

(2) *Turkeys—(i) Amount.* Administer in drinking water to provide 50 to 124 mg/lb of body weight per day

(ii) *Indications for use.* For control of coccidiosis (*E. meleagrimitis*, *E. adenoeides*).

(iii) *Limitations.* Add the required dose to that amount of water that will be consumed in 1 day. Consumption should be carefully checked. Have only medicated water available during treatment. Withdraw medication 10 days prior to slaughter for food. Do not medicate turkeys producing eggs for human consumption. Treatment of all diseases should be instituted early. Treatment should continue 24 to 48 hours beyond the remission of disease symptoms. Medicated turkeys must actually consume enough medicated water which provides the recommended dosages.

(3) *Swine—(i) Amount.* Administer in drinking water, or as a drench, to provide 108 mg/lb of body weight on the first day and 54 mg/lb of body weight per day on the second, third, and fourth days of administration.

(ii) *Indications for use.* For treatment of porcine colibacillosis (bacterial scours) (*E. coli*), and bacterial pneumonia (*Pasteurella* spp.).

(iii) *Limitations.* Add the required dose to that amount of water that will be consumed in 1 day. Consumption should be carefully checked. Have only medicated water available during treatment. Withdraw medication 15 days prior to slaughter for food. Treatment of all diseases should be instituted early. Treatment should continue 24 to 48 hours beyond the remission of disease symptoms, but not to exceed a total of 5 consecutive days.